An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Working Paper: Inpatient Acute Care Hospital Services
Medical/Surgical and Pediatric Services

Analysis of Public Comments and Staff Recommendation

MARYLAND HEALTH CARE COMMISSION
Division of Health Resources
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Summary and Analysis of Public Comments and Staff Recommendation on An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Working Paper: Inpatient Acute Care Services (Medical-Surgical and Pediatric Services)

I. Introduction

With the passage of House Bill 995, the General Assembly required the Maryland Health Care Commission to examine the major policy issues of the Certificate of Need process, and to submit an interim report by January 1, 2001, followed by a final report by January 1, 2002. The Commission embarked upon a two-year process during which it would develop a series of working papers examining specific issues and implications of changes to the CON model of regulation. The *Working Paper: Inpatient Acute Care Services (Medical-Surgical and Pediatric Services)* was one in a series of working papers prepared as part of this overall CON program study. This working paper provided the basis for public comment on whether changes are needed with respect to CON regulation of acute care hospitals.

The working paper presents several potential options for government oversight of acute care hospitals, including medical-surgical and pediatric services. The options are as follows:

Acute Care Hospitals (Medical-Surgical Services)

Option 1: Maintain Existing Certificate of Need Program Regulation
Option 2: Expanded Certificate of Need Program Regulation For Acute Care Hospital Closures
Option 3: Expand Certificate of Need Program Regulation for Major Hospital Capital Projects by Eliminating the "Pledge"
Option 4: Modify Certificate of Need Review by Eliminating or Reducing the Flexibility Provided to Merged Hospital Systems
Option 5: Reduce Certificate of Need Review by Increasing the Capital Review Threshold to $2.5 Million
Option 6: Deregulation With Creation of Data Collection and Reporting Model to Assure Quality
Option 7: Deregulation with Creation of Licensure Standards
Option 8: Deregulation of Acute Care Hospitals from Certificate of Need Review

Pediatric Services

Option 1: Maintain Existing Certificate of Need Program Regulation
Option 2: Expand Certificate of Need Program Regulation for Pediatric Service Closures
Option 3: Maintain Existing Certificate of Need Program Regulation, with Regional Need Projection
Option 4: Modified Certificate of Need Oversight
Option 5: Deregulation with Creation of a Data Collection and Reporting Model to Assure Quality
Option 6: Deregulation with Creation of Licensure Standards
Option 7: Deregulation of Pediatric Services from Certificate of Need Review

The Commission released this working paper for public comment on July 19, 2001, and invited interested organizations and individuals to submit written comments through August 20, 2001. In response to this invitation, the Commission received comments from the following organizations:

- Adventist Healthcare
- Anne Arundel Medical Center
- Carroll County General Hospital
- Dimensions Healthcare System
- Gallagher, Evelius & Jones (Representing Doctors Community Hopsital, North Arundel Hospital, Suburban Hospital, and University of Maryland Medical System)
- Garrett County Memorial Hospital
- Greater Baltimore Medical Center
- Holy Cross Health
- Howard County Board of Health
- Johns Hopkins Health System
- LifeBridge Health
- Association of Maryland Hospitals and Health Systems
- MedStar Health
- St. Agnes Health Care

The public comments are summarized in Part II. Staff analysis of the public comments is provided in Part III. A staff recommendation is provided in Part IV. To provide an opportunity for additional input, the staff recommendations will be released for public comment. The Commission invites all interested organizations and individuals to submit comments on the staff recommendations presented in this document. Written comments should be submitted no later than **Friday, October 5, 2001** to:

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II. Summary of Public Comments[1]

Acute Care Hospitals (Medical/Surgical Services)

Option 1- Maintain Existing Certificate of Need Program Regulation

Comments submitted by **Adventist Healthcare** *support* Option 1. Of the ten policy options specifically offered for medical-surgical services, Adventist Healthcare believes that Option 1 provides the best guarantee of preservation of the principles which have been the foundation of health planning in the State for many years; namely, quality, access, and affordability. The existing system of CON regulation specifically for these secondary level services creates an environment of stability, reliability, and high quality healthcare for patients in Maryland. Adventist Healthcare would also like to encourage the Commission to incorporate changes that would require data collection and reporting that provides meaningful information about the quality of healthcare provided in Maryland.

Anne Arundel Medical Center (AAMC) *opposed* Option 1. AAMC does not believe that this is a viable alternative. The existing CON system for medical-surgical, gynecological services has been marked almost entirely by inaction or selection of the pledge as an alternative to CON. This is not accidental. The pledge was adopted largely in response to the past history of the expense and difficulty of complying with CON laws and an extremely cumbersome and almost always antiquated State Health Plan. While staff should be commended for streamlining the CON process over the years, the State Health Plan in its current iteration is severely antiquated and, if strictly applied, would frustrate any modern health care project

The **Association of Maryland Hospitals and Health Systems** *supports* this option. There is nothing occurring either now or in the foreseeable future in our acute care environment that warrants changing the regulatory structure.

Dimensions Healthcare System wrote in *support* of this option.

Garrett County Memorial Hospital wrote in *support* of maintaining the current system.

GMBC *opposed* Option 1. GBMC believes that quality of care would be better served through a licensing or certification process rather than the current CON process. CON policies provide oversight only prior to market entry with no meaningful ongoing quality of care requirements or monitoring. The current process controls the entry of new providers based only on projected need, a policy unrelated to their ability of provide quality of care. The current CON process does not allow for the enforcement of compliance to CON criteria subsequent to CON approval.

[1] A complete set of the written comments may be obtained by contacting the Maryland Health Care Commission, Health Resources Division at 410-764-3232.

Holy Cross Hospital (HCH) wrote in *support* of maintaining the CON program. HCH believes that maintaining the CON is beneficial to the State. However, HCH wrote that enacting some of the changes discussed in the other options could strengthen the program.

Howard County Board of Health *supports* this option. As current CON regulation is working well, the Board is in favor of maintaining the status quo with respect to these services.

Johns Hopkins Health System *supports* maintaining a set of core CON program regulations but with some flexibility in order to promote efficiencies and reduce administrative burdens and expenses for both the providers and the Commission.

LifeBridge Health *supports* continued CON regulation of the establishment of new medical/surgical facilities and the relocation of existing facilities. The continuation of CON is important to ensure that access of quality and cost-effective care is maintained throughout the State. As the experience of other states has shown, without an effective CON review process, new specialty or short stay hospitals, typically under for-profit ownership and often with investment from referring physicians, can be developed for the purpose of "skimming" off profitable service lines, leaving the general acute care facilities with the responsibilities and financial burden associate with remunerative services. Such a system would pose a serious threat to the financial health of Maryland hospitals.

MedStar Health *supports* Option 1, which maintains the CON program regulation as it is currently applied, to all projects except those that only require a CON because they exceed the capital expenditures threshold.

St. Agnes HealthCare *supports* maintaining the existing CON program for medical/surgical services. Due to the volatile market dynamics that acute care providers are facing, St. Agnes believes that the Commission should maintain the existing level of CON and regulatory oversight for medical/surgical services. The existing framework provides the Commission with the regulatory flexibility to respond to the needs of hospital providers as they navigate the constantly shifting landscape of the health care environment.

‣ Option 2- Expand Certificate of Need Program Regulation for Acute Care Hospital Closures

Anne Arundel Medical Center (AAMC) *did not take a position* on Option 2. However, AAMC noted that they had gone through the process of obtaining approval to close a service in the past. AAMC also indicated their belief that Maryland's not-for-profit hospitals will not close any service that is both needed by and supported by the public. In an age where it is increasingly difficult for hospitals to maintain the margin that is required for them to continue to provide needed services, a system that adds cost and time to closing services which are neither needed nor supported by the community is not in the public interest.

The **Association of Maryland Hospitals and Health Systems** *opposed* this option. Neither the text of this working paper nor previous papers, have discussed problems or concerns with hospital closures in the past two years that would warrant the need for CON.

Dimensions Healthcare System wrote in *opposition* to this option

GBMC *opposed* this option based on the reasons for their opposition to Option 1.

Holy Cross Hospital (HCH) *opposed* this proposal. Closing a hospital, even in jurisdictions with multiple hospitals, can have a significant impact on the community. HCH believes it is appropriate to develop a plan to address any problems related to access that the proposed hospital closure will create. However, the CON process is not necessarily the best vehicle for developing such a plan.

MedStar Health *opposes* Option 2, because MedStar believes that current provisions for public notification and involvement (and CON exemption in counties with 1 or 2 hospitals) is adequate.

‣ Option 3 - Expand Certificate of Need Program Regulation for Major Hospital Capital Projects by Eliminating the "Pledge"

Anne Arundel Medical Center (AAMC) *opposed* eliminating the pledge. AAMC and almost every other hospital in the State of Maryland has used the pledge at one time or another in order to proceed with a project which the hospital believed either would not be approved or would not be approved in a timely fashion through the CON process. The pledge, therefore, has served a very valuable purpose.

The **Association of Maryland Hospitals and Health Systems** *opposed* this option. There is no discussion in the text of this working paper to indicate that a major regulatory problem exists with hospitals using the pledge. The working paper indicates that the pledge has been used many times by hospitals over the last ten years. Further, we do know that more and more hospitals are opting to pursue CON now for capital projects because they do ultimately want to get approved to include the costs in rates.

Carroll County General Hospital (CCGH) *supports* eliminating the "Pledge". CCGH does not believe that the pledge exemption serves a useful purpose for health care cost control any longer because of the significant changes and restrictions in the rate setting system. The pledge process circumvents the CON system without demonstrating a significant contribution to industry efficiencies.

Dimensions Healthcare System wrote in *opposition* to this option

GBMC *opposed* eliminating the "Pledge" best serves the interests of the citizens of Maryland. The ability to take the "Pledge" allows hospitals to respond quickly to meet the changing needs of their communities. Eliminating the "Pledge" would only serve to increase the

number of applications in the Commission's queue, slowing down the development of services that are critical to the health of the communities that these organizations serve.

Holy Cross Hospital *opposed* this option. Expanding the CON program review for projects that will not significantly affect costs adds an unnecessary burden on both the institutions and the Commission with minimal benefit.

Johns Hopkins Health System *opposed* eliminating the "Pledge".

MedStar Health *opposed* Option 3, because MedStar does not believe that the public has the same compelling interest in capital expenditures that they do in the development of health care services. In the case of relatively small capital expenditure projects, MedStar believes that the interest of hospitals to react to the constantly changing health care environment outweighs the interest of the public in regulating these expenditures.

‣ Option 4– Modify Certificate of Need Review by Eliminating or Reducing the Flexibility Provided to Merged Hospital Systems

Anne Arundel Medical Center (AAMC) *supported* this option. AAMC does not believe that there is any continuing need to include the incentives given to merger and consolidation originally adopted in 1985. The health landscape has changed sufficiently since that time to remove the need for the special preferences contained in the 1985 legislation.

The **Association of Maryland Hospitals and Health Systems (MHA)** strongly *opposed* this option. There is no discussion in the text of this working paper about the pros and cons of this proposal. MHA argues that the reasons outlined in the paper for the allowed flexibility still exist and should continue.

Carroll County General Hospital (CCGH) *supports* eliminating or reducing the flexibility provided to merged asset systems. These preferences were added to Maryland law on the assumption that the health care system would benefit from hospital consolidations and mergers by way of voluntary reductions in excess hospital capacity and lower costs. There is no evidence of which CCGH is aware that this has been the result in the more than fifteen years that have passed since the health policy was put into Maryland law.

Dimensions Healthcare System wrote in *opposition* to this option

GBMC *does not support* this option. If CON remains, GBMC believes that all hospital projects, regardless of whether undertaken by merged assets system or an unaffiliated hospital, should be subject to the level of scrutiny provided by the CON process.

Holy Cross Hospital (HCH) *supports* this option. Making this change would eliminate the current two-tiered system of review that disadvantages stand-alone hospitals. If there is benefits from the proposed project that result from being part of a merged asset system, they should be presented and evaluated as part of the CON process.

Johns Hopkins Health System *opposed* modifying or otherwise eliminating the flexibility to reconfigure beds or services or undertake major capital expenditures provided to merged hospital systems under the current law. This flexibility is necessary in order for merged hospital systems to respond appropriately and effectively to the market, and to promote the natural efficiencies that occur in a merger but which often take a substantial amount of time to identify and realize.

MedStar Health *opposes* this option. MedStar believes that the exemption granted to merged asset systems have helped them to voluntarily reduce excess bed capacity and lower the cost of providing care in the State. MedStar does not believe, however, that merged asset systems should allow the movement of hospital beds between jurisdictions and the establishment of new services through the relocation of beds.

‣ Option 5- Reduce Certificate of Need Review by Increasing the Capital Review Threshold to $2.5 Million

Anne Arundel Medical Center (AMC) *supports this option*, but believes that the $2.5 million dollar threshold proposed is insufficient. Hospitals are very large organizations, with very large capital needs. AAMC would support a higher number based upon a review of capital expenditures by hospitals, so that ordinary and normal hospital expenditures would be excluded from review. AAMC believes that such a review would indicate that the threshold should be at least $3.5 million and possibly higher.

Carroll County General Hospital *supports* this option. The Hospital believes that it would allow flexibility for hospitals in their capital projects and preserve the value of the CON process for appropriately complex and substantial capital projects.

Dimensions Healthcare System wrote in *support* of this option

Garrett County Memorial Hospital wrote in *support* of raising the review threshold to $2.5 million. The current financial threshold is too low in light of today's inflated construction/labor costs. Raising the threshold would maintain current administrative standards but would provide a more reasonable dollar limit for review.

GBMC *supports* this option. The Hospital believes that it would allow for the staff to focus attention on larger projects that would have a greater potential to impact the health care system.

Holy Cross Hospital *supports* this option, because a higher capital review threshold would appropriately focus attention on larger projects with a greater future impact on the health care system.

Johns Hopkins Health System writes *in support* of raising the capital threshold to $2.5 million. Increasing the capital threshold should not result in a flood of new services into the

market place provided the new threshold is not excessively high. The threshold should be increased to promote efficiencies and reasonable flexibility for providers but should not be significantly high to create an economic incentive for providers to expand new services or into new markets without a demonstrable need.

LifeBridge Health *supports* this option. Because the exercise of this option has become almost routine, the Hospital believes the Commission should consider eliminating the requirement that hospitals affirmatively seek an exemption determination for projects in excess of the capital threshold. That is, the Commission should consider permitting hospitals to undertake capital expenditures, regardless of amount, without CON review, but with a stipulation that hospitals will be precluded from seeking a rate increase on the basis of that expenditure for a defined period, such as 10 years.

MedStar Health *supports* this option. MedStar believes that the Commission should raise the existing capital expenditures threshold of $1.45 million to $2.5 million in order to increase hospitals' flexibility to initiate relatively small capital expenditure projects.

‣ Option 6 - Deregulation with Creation of a Data Collection and Reporting Model to Assure Quality

Anne Arundel Medical Center (AAMC*) opposed* this option. AAMC believes that this option confuses quality assurance activities with Certificate of Need. Quality is a very difficult thing to measure. If a fair, equitable, and accurate system could be devised for measuring quality, AAMC would have no objection to this option. However, AAMC does not believe than any such system exists. A bad system is far worse than none at all.

Dimensions Healthcare System wrote in *opposition* to this option

GBMC *does not agree* with replacing the CON program's requirements governing market entry and exit with a program of mandatory collection and reporting. This option would rely on consumer or provider report cards/performance reports to regulate the quality of care in the Maryland health care system. Unfortunately, such a mechanism would not assure the quality of care when a new provider enters the market and it would not be responsive to situations where there is a decline in quality over time.

Holy Cross Hospital (HCH) *does not support* this option. HCH believes that CON process provides a valuable public function and should be maintained. Data collection and dissemination can be very valuable, but it is not a substitute for CON oversight.

Johns Hopkins Health System *does not support* this option. Provided there is proper industry participation in the development of the criteria to measure and monitor the quality of care, Hopkins would consider supporting the establishment of a data collection and feedback system designed for use by providers, although such quality measurements should not serve as a replacement for the CON program. However, such performance reports and quality measures could be built into the CON evaluation process.

Comments from **MedStar Health** *oppose* Option 6 as an alternative to CON. These quality measures place the onus on the patient and fail to adequately convey information that is critical to statewide planning like geographic and financial access to services, and cost-effectiveness of care.

‣ Option 7- Deregulation with Creation of Licensure Standards

Anne Arundel Medical Center (AAMC) *does not support* this proposal if it is only adopted for medical/surgical services. AAMC would only support this proposal if it covered all services, because AAMC does not believe that the Office of Health Care Quality has either the staffing or expertise to develop and monitor licensing standards for medical, surgical, gynecological and pediatric services. The Hospital does not believe that the public would derive any benefit from the creation of an extensive licensure system governing medical, surgical, and gynecological services.

Dimensions Healthcare System wrote in *opposition* to this option

GBMC *support*s Option 7. GBMC believes that deregulation with the creation of licensure standards is the preferred regulatory policy option to ensure that the citizens of Maryland receive the best quality health care services. Licensure could be structured to provide appropriate regulatory oversight by establishing the standards for entry into the market, but also for regular monitoring. Ongoing licensure review would be based upon volume and mortality standards and guidelines for quality care developed by the appropriate clinical organizations.

Holy Cross Hospital (HCH) *does not support* this option. HCH writes that licensure is important and has a defined role in ensuring that outcome and quality standards are met. It does not however substitute for a rational planning process.

This option is *unacceptable* to **MedStar Health**. This option does not adequately protect the accessibility of high-quality, cost-effective care, and it would likely result in an oversupply of expensive, specialized services in urban centers of the State.

‣ Option 8 – Deregulation of Acute Care Hospitals from Certificate of Need Review

Anne Arundel Medical Center *is opposed* to the absolute elimination of Certificate of Need review for the creation or relocation of acute care hospitals.

Dimensions Healthcare System wrote in *opposition* to this option

GBMC *does not support* the removal of the CON process without replacement by another regulatory tool, such a licensure or certification. To ensure the citizens of Maryland receive the best quality health care, it is necessary to have a regulatory mechanism in place that establishes and monitors compliance to well defined medically sound quality care standards.

Holy Cross Hospital (HCH) *does not support* this option. HCH believes that maintaining the CON is beneficial to the State.

This option is *unacceptable* to **MedStar Health**. This option does not adequately protect the accessibility of high-quality, cost-effective care, and it would likely result in an oversupply of expensive, specialized services in urban centers of the State.

Additional Option

Anne Arundel Medical Center has proposed that the Commission should permit hospitals to voluntarily propose, develop and have approved institution-specific plans on a five-year or longer term. Once the Commission approves the institution specific plan for a hospital, the hospital would proceed during that five-year horizon to implement that plan whether it includes change of services, capital projects, or a combination of the above. An institution specific plan would permit hospitals to more effectively plan for the future, and to develop those plans recognizing that changes between concept and completion are certain to occur.

Pediatrics

Option 1- Maintain Existing Certificate of Need Program Regulation

Anne Arundel Medical Center (AAMC) *wrote in opposition* to Option 1. AAMC does not believe that this is a viable alternative. The existing CON system for pediatric services has been marked almost entirely by inaction or selection of the pledge as an alternative to CON. This is not accidental. The pledge was adopted largely in response to the past history of the expense and difficulty of complying with CON laws and an extremely cumbersome and almost always antiquated State Health Plan. While staff should be commended for streamlining the CON process over the years, the State Health Plan in its current iteration is severely antiquated and, if strictly applied, would frustrate any modern health care project.

Comments submitted by **Adventist Healthcare** *supported* Option 1. Adventist Healthcare believes Option 1 provides the strongest assurance to Maryland patients of healthcare that is high quality, accessible, and affordable. Adventist Healthcare would also like to encourage the Commission to incorporate changes that would require data collection and reporting that provides meaningful information about the quality of healthcare provided in Maryland.

Dimensions Healthcare System wrote in *support* of this option.

GBMC *does not support* this option. GBMC believes that quality of care would be better served through a licensing or certification process rather than the current CON process. CON policies provide oversight only prior to market entry with no meaningful ongoing quality of care requirements or monitoring. The current process controls the entry of new providers based only on projected need, a policy unrelated to their ability of provide quality of care. The current CON

process does not allow for the enforcement of compliance to CON criteria subsequent to CON approval

Garrett County Memorial Hospital wrote in *support* of maintaining the current system.

Holy Cross Hospital (HCH) wrote in *support* of maintaining the CON program. HCH believes that maintaining the CON is beneficial to the State. However, HCH wrote that enacting some of the changes discussed in the other options could strengthen the program.

Howard County Board of Health *supports* this option. As current CON regulation is working well, the Board is in favor of maintaining the status quo with respect to these services.

Johns Hopkins Health System *supports* maintaining the existing CON program for pediatric services. The Commission should continue to include a bed need projection methodology and the projections of excess pediatric bed capacity in the State Health Plan.

LifeBridge Health *supports* the continuation of the current level of CON oversight for general pediatric beds. However, at least in Central Maryland, existing CON authority is of little practical effect, in that only a handful of hospitals do not currently have pediatric beds, and it is unlikely that any of the hospital without such beds will seek to initiate an inpatient pediatric program at any time in the near future.

MedStar Health *supports* maintaining the existing CON program for pediatric services. The current system provides adequate protections for the public and allows a reasonable degree of flexibility for unaffiliated and merged asset systems. Pediatrics is a fundamental hospital service that should be available locally.

St. Agnes HealthCare *supports* maintaining the existing CON program for pediatrics. Due to the volatile market dynamics that acute care providers are facing, St. Agnes believes that the Commission should maintain the existing level of CON and regulatory oversight for pediatric services. The exisiting framework provides the Commission with the regulatory flexibility to respond to the needs of hospital providers as they navigate the constanaly shifting landscape of the health care environment.

‣ Option 2 - Expand Certificate of Need Program Regulation for Pediatric Service Closures

Anne Arundel Medical Center (AAMC) *did not take a position* on Option 2. However, AAMC noted that they had gone through the process of obtaining approval to close a service in the past. AAMC also indicated their belief that Maryland's not-for-profit hospitals will not close any service that is both needed by and supported by the public. In an age where it is increasingly difficult for hospitals to maintain the margin that is required for them to continue to provide needed services, a system that adds cost and time to closing services which are neither needed nor supported by the community is not in the public interest.

Dimensions Healthcare System wrote in *opposition* to this option.

GBMC *does not support* this option based on the reasons for their opposition to Option 1.

Holy Cross Hospital (HCH) *does not support* this proposal. Closing a hospital, even in jurisdictions with multiple hospitals, can have a significant impact on the community. HCH believes it is appropriate to develop a plan to address any problems related to access that the proposed hospital closure will create. However, the CON process is not necessarily the best vehicle for developing such a plan.

‣ Option 3 - Maintain Existing Certificate of Need Program Regulation, With Regional Need Projections

Dimensions Healthcare System wrote in *opposition* of this option.

GBMC *does not support* this option. This option permits hospitals in a merged system to move pediatric beds within the system anywhere within a region without a CON; however, it continues CON for hospitals not in a merged system. The proposal would benefit only those hospitals within a system with a partner located in the same region but not in the same county.

Holy Cross Hospital (HCH) *wrote in opposition* to this option. HCH is concerned about broadening the area for need projections from a jurisdiction o the region. According to Holy Cross, pediatric services require close family involvement. The Hospital's concern is that by moving to a regional approach, families could be required to travel significant distances without improving access and quality.

Johns Hopkins Health System *supports* revising the CON regulations so that the bed need projection methodology for pediatric services is on a regional basis rather than a jurisdictional (county) basis, and the CON applications are reviewed against the standards and policies in the State Health Plan. Projecting need on a regional basis would allow the Commission to focus need on true patient migration patterns.

‣ Option 4- Modified Certificate of Need Oversight

Dimensions Healthcare System wrote in *opposition* of this option.

GBMC *does not support* this option and the continuation of CON. If the effect of the current CON process on the health care system is negatively impacting access or the continuity of care related to pediatric services it should be corrected or replaced.

Holy Cross Hospital *does not support* eliminating the need threshold. Holy Cross Hospital states that pediatric care is a specialty service. To be delivered effectively, it requires a critical mass of skilled staff, equipment and support services. Eliminating the need threshold would increase costs to the health care system without improving access or quality.

‣ Option 5 - Deregulation with Creation of a Data Collection and Reporting Model to Assure Quality

Anne Arundel Medical Center (AAMC*) is opposed* to this option. AAMC believes that this option confuses quality assurance activities with Certificate of Need. Quality is a very difficult thing to measure. If a fair, equitable, and accurate system could be devised for measuring quality, AAMC would have no objection to this option. However, AAMC does not believe than any such system exists. A bad system is far worse than none at all.

Dimensions Healthcare System wrote in *opposition* of this option.

GBMC *does not agree* with replacing the CON program's requirements governing market entry and exit with a program of mandatory collection and reporting. This option would rely on consumer or provider report cards/performance reports to regulate the quality of care in the Maryland health care system. Unfortunately, such a mechanism would not assure the quality of care when a new provider enters the market and it would not be responsive to situations where there is a decline in quality over time.

Holy Cross Hospital (HCH) *does not support* this option. HCH believes that CON process provides a valuable public function and should be maintained. Data collection and dissemination can be very valuable, but it is not a substitute for CON oversight.

‣ Option 6- Deregulation with the Creation of Licensure Standards

Dimensions Healthcare System wrote in *opposition* of this option.

Comments submitted by **GBMC** *support* Option 6. GBMC believes that deregulation with the creation of licensure standards is the preferred regulatory policy option to ensure that the citizens of Maryland receive the best quality health care services. Licensure could be structured to provide appropriate regulatory oversight by establishing the standards for entry into the market, but also for regular monitoring.

Holy Cross Hospital (HCH) *does not support* this option. HCH believes that CON process provides a valuable public function and should be maintained. Data collection and dissemination can be very valuable, but it is not a substitute for CON oversight. However, given the specialty nature of pediatric services, periodic review of compliance with standards and of quality outcomes may be appropriate.

‣ Option 7- Deregulation of Pediatric Services from Certificate of Need Review

Anne Arundel Medical Center (AAMC) *does not support* this proposal if it is only adopted for pediatric services. AAMC would only support this proposal if it covered all services, because AAMC does not believe that the Office of Health Care Quality has either the staffing or expertise to develop and monitor licensing standards for pediatric services. The

Hospital does not believe that the public would derive any benefit from the creation of an extensive licensure system governing medical, surgical, and gynecological services.

Dimensions Healthcare System wrote in *opposition* to this option.

Doctor's Community Hospital *supports* this option. Pediatric is a basic hospital service, which is offered by the majority of Maryland hospitals, and every Maryland based hospital system. Existing hospitals that want to add pediatrics to provide an additional basic service to the communities they serve should be allowed to do so without obtaining a CON, so long as they do so within their HSCRC approved charge per case.

GBMC *does not support* the removal of the CON process without replacement by another regulatory tool, such a licensure or certification. To ensure the citizens of Maryland receive the best quality health care, it is necessary to have a regulatory mechanism in place that establishes and monitors compliance to well defined medically sound quality care standards.

Holy Cross Hospital (HCH) *does not support* this option. HCH believes that CON process provides a valuable public function and should be maintained. Data collection and dissemination can be very valuable, but it is not a substitute for CON oversight.

North Arundel Hospital *supports* this option. Pediatric is a basic hospital service, which is offered by the majority of Maryland hospitals, and every Maryland based hospital system. Existing hospitals that want to add pediatrics to provide an additional basic service to the communities they serve should be allowed to do so without obtaining a CON, so long as they do so within their HSCRC approved charge per case.

Suburban Hospital *supports* this option. Pediatric is a basic hospital service, which is offered by the majority of Maryland hospitals, and every Maryland based hospital system. Existing hospitals that want to add pediatrics to provide an additional basic service to the communities they serve should be allowed to do so without obtaining a CON, so long as they do so within their HSCRC approved charge per case.

University of Maryland Medical System *supports* this option. Pediatric is a basic hospital service, which is offered by the majority of Maryland hospitals, and every Maryland based hospital system. Existing hospitals that want to add pediatrics to provide an additional basic service to the communities they serve should be allowed to do so without obtaining a CON, so long as they do so within their HSCRC approved charge per case.

Additional Option

LifeBridge Health suggests that CON approval be required for the establishment of a new pediatric intensive care unit. While LifeBridge Health does not believe that approvals should be tied to specific need and capacity formula, we believe that hospitals seeking to establish a pediatric intensive care unit should be required to explain how that program will enhance the quality and cost effectiveness of pediatric care within the affected regional planning

region, and to demonstrate that the proposed unit will not have a material negative impact on existing providers.

III. Staff Analysis of Public Comments

Acute Care Hospitals (Medical-Surgical Services)

Twelve organizations submitted comments on Option 1 in the working paper. This option would maintain the Certificate of Need program as currently applied to acute general hospitals. Under current health planning law, a Certificate of Need is required to develop a new acute care hospital facility. For existing acute care hospitals, a Certificate of Need would not be required for capital projects involving new construction or renovation over the review threshold (currently $1.45 million) provided that the hospital agrees not to increase patient charges or rates more than $1.5 million over the entire period or schedule of debt service associated with the project. The Commission makes this determination after consultation with the Health Services Cost Review Commission. For capital projects over the review threshold at an existing hospital, a Certificate of Need would be required if the hospital plans to seek a rate increase or desires to preserve the option to seek a future rate increase.

Ten of the organizations commenting on Option 1 wrote in support of maintaining the existing regulatory system for acute care hospitals. In support of maintaining the current system, comments noted that the existing system of CON oversight is working well and creates an environment of stability, reliability, and high quality health care for patients. It was noted that nothing occurring either now or in the foreseeable future warrants changing the regulatory system. In addition, the comments noted that the experience of other states has shown that without an effective CON review process, new specialty or short-stay hospitals, typically under for-profit ownership and often with investment from referring physicians, can be developed for the purpose of "skimming" off profitable service lines.

Two organizations submitted comments opposing Option 1. Comments in opposition to maintaining the existing CON program indicated that the existing system has been marked almost entirely by inaction or selection of the pledge as an alternative to CON. The pledge, as an alternative to CON, was adopted because of the difficulty and expense of complying with CON laws and an extremely cumbersome and almost always antiquated State Health Plan. In opposition to the existing CON system, it was also noted that quality of care would be better served through a licensing or certification process rather than the current CON process.

Under current health planning law, the closure of an acute care hospital requires either a 45-day notice or an exemption from CON review. Upgrading the Commission's role in the approval of an acute care hospital closure is an alternative regulatory strategy discussed in Option 2. The five of the six comments received on this option were in opposition to expanding the Commission's role with respect to closures as outlined in Option 2. Another expansion of CON oversight was proposed in Option 3. In Option 3, regulatory oversight of hospital capital expenditures would increase by eliminating the ability to take the "Pledge". Acute care hospitals are not required to obtain a Certificate of Need for capital projects involving new construction or

renovation over the review threshold provided that the hospital agrees not to increase patient charges or rates. A total of eight comments were received on Option 3. Seven of the eight comments opposed eliminating the pledge.

The working paper included two options designed to maintain the existing CON program with modification. Option 4 proposed modifying the CON program by eliminating or reducing the flexibility provided to merged hospital systems. Currently, merged hospital systems may be granted exemptions from CON review for projects pursuant to a consolidation or merger if three statutory criteria are met. These criteria require that the proposed change is not inconsistent with the State Health Plan, is efficient and effective, and is in the public interest. The eight comments received on Option 4 were evenly divided with four in support and four in opposition to modifying current practice regarding merged hospital systems. Another modification to the current CON program, suggested in Option 5, would increase the capital review threshold in statute from $1.25 to $2.5 million. All nine comments received on this option supported an increase in the capital review threshold.

The final three options outlined in the working paper proposed different approaches to deregulating medical-surgical services from CON review. In Option 6, deregulation from CON review was combined with a data reporting model emphasizing quality measurement. Six hospitals commented on this option and all were opposed to this model of oversight. Deregulation from CON review combined with a licensure program was proposed in Option 7. Of the five hospitals commenting on this option, one hospital was in support and four were in opposition. The final option, suggesting total deregulation, received no support from the five organizations commenting.

Comments received regarding CON regulation of acute care hospitals focused on several issues. First, the issue of whether CON oversight of acute care hospitals should be replaced by a licensure program was raised in the comments. Comments received suggested that quality of care would be better served through a licensing or certification process rather than the current CON process. It is important to recognize that the CON program is a tool designed to regulate entry into the health care market. The CON program is not a tool designed for on-going quality monitoring. Staff believes that the CON program and improved oversight through an enhanced licensure program are not mutually exclusive. With respect to the CON program, the question is whether there is a benefit to the public in examining community need and impact on the health care system for new acute care hospitals and services prior to developing those facilities. Because of the expense of acute care hospital facilities and their importance to the community, staff believes that there is a compelling public policy interest in controlling the supply and avoiding unnecessary duplication hospital facilities and services. Moreover, staff believes that a major advantage of the CON program is the opportunity to provide a level of accountability to determine whether new hospitals and services are needed and will have a positive impact on the health care system.

A second issue raised in the comments concerns the capital review threshold. Option 5 suggests increasing the capital review threshold to $2.5 million for acute care hospitals. The former Planning Commission's original enabling statute (Ch. 108, Acts of 1982) set the capital review threshold at $600,000; this was amended in 1988 (Chs. 688 and 767, Acts of 1988) to

$1,250,000.[2] After indexing for inflation, the capital review threshold is now $1,450,000. Given the differences in the industries regulated by the Commission, staff believes that it would be appropriate to consider a higher capital threshold for acute care hospitals. Analysis of hospital CON projects and determinations of non-coverage issued between 1990-2001 indicate that a small number were under $2.5 million. Over this time period, only 19 (14.2 percent) of the 134 hospital capital projects submitted to the Commission for review were below $2.5 million. Staff believes that increasing the capital review threshold to $2.5 million for acute care hospitals would appropriately focus attention on the more expensive projects with a larger impact.

Another issue discussed in the comments concerns the procedural advantages provided to merged asset systems. Incentives to encourage the merger and consolidation of acute care hospitals in Maryland originated from the 1985 Health Care Cost Containment Act-Hospital Mergers and Consolidations. The comments on the working paper question whether the advantages given to merged asset systems should be maintained in the future. A study entitled *Hospital Mergers and Savings for Consumers: Exploring New Evidence* submitted by a commenter concludes that the cost and price savings resulting from mergers may be significantly smaller than estimated in earlier studies.

There are nine merged hospital systems currently operating in Maryland. These systems, defined as multiple-hospital systems under common management and governance, now include one-half (23) of the 47 licensed acute care hospitals in Maryland. The three largest merged asset hospital systems (Johns Hopkins Health System, MedStar Health, and University of Maryland Medical System) account for one-third of total licensed acute care beds in Maryland as of July 1, 2001. Staff believes that it would be appropriate to conduct a more in-depth analysis of the benefits of merged asset systems to guide future regulatory policies. The pending update of the acute inpatient services chapter of the State Health Plan would be an appropriate vehicle to examine the issues raised in the comments with respect to merged asset systems.

Finally, a number of commenters addressed the process of taking the "Pledge" not to increase rates for hospital capital projects. Under current health planning law, acute care hospitals are not required to obtain a Certificate of Need for capital projects involving new construction or renovation over the review threshold provided that the hospital agrees not to increase patient charges or rates more than $1.5 million. Option 3 would expand Certificate of Need oversight of hospital capital projects by requiring Commission review and approval of all capital projects over the threshold. Several commenters noted that recent changes in the rate-setting environment may change future incentives regarding the "Pledge". Staff believes that the "Pledge' should be maintained. At the same time, staff recognizes the need to work closely with HSCRC and the hospital industry to monitor the issues raised in the comments on the impact of changes in the rate-setting system.

[2] The revision to CON procedural regulations effective November 6, 1995 added to the definition of "threshold for capital expenditures" the phrase "for 1995, after that to be adjusted annually by the Commission according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest $50,000.

Pediatrics

Eleven organizations submitted comments on Option 1 in the working paper. This option would maintain the Certificate of Need program as currently designed. Under current law, a CON is required to establish a new pediatric service in a hospital that is not a member of a merged asset system reconfiguring services. Nine of the comments supported maintaining the existing CON system for pediatric services. Two comments opposed the existing CON program for pediatric services.

The closure of a pediatric service requires either a 45-day notice or an exemption from CON review under current law. Upgrading the Commission's role in prior approval of pediatric service closures is an alternative regulatory strategy. A finding by the Commission that exempts a proposed hospital service closure from CON review is currently needed in jurisdictions with one or two hospitals; only notice to the Commission and a public hearing is necessary for a service closure in a multiple hospital jurisdiction. Option 2 would strengthen current oversight of pediatric service closures by requiring hospitals in multiple hospital jurisdictions to obtain an exemption to exit the market. Four hospitals commented on this option for pediatric services and all were opposed to expanding CON oversight for market exit.

The third option involves changing the policies in the bed need projection methodology to project need for pediatric services on a regional rather than a jurisdictional basis. Currently the SHP projects need for pediatric beds on a jurisdictional (county) basis, and CON applications are reviewed against the standards and policies in the SHP. The four comments received on this option were evenly divided with two in favor and two opposed.

Another option is to modify the standards under which proposals to establish new pediatric programs are reviewed, while retaining Commission authority to establish standards for access, quality, and cost effectiveness. Option 4, which is similar to the recommendation adopted by the Commission for acute inpatient obstetrics services, would change the State Health Plan to remove the threshold need requirement. The three organizations commenting on Option 4 were all opposed to this modification.

The final three options outlined in the working paper proposed different approaches to deregulating pediatric services from CON review. In Option 5, deregulation would be combined with a data collection and reporting model to assure quality. Four hospital submitted comments on this option and all were opposed. Under Option 6, the role of government oversight would shift from regulating market entry and exit to monitoring the on-going performance of the pediatric service through the development of licensure standards. Two of the three hospitals commenting on this regulatory approach were in support and one hospital was opposed. Finally, the total deregulation of pediatric services from CON review was outlined in Option 7. A total of eight hospitals commented on this option. Four of those comments supported total deregulation of pediatric services from CON review. The remaining four opposed deregulation of pediatric services.

The advantages and disadvantages of deregulating pediatric services from CON review are discussed in a number of the public comments received on the working paper. Fourteen of

the 47 non-federal, acute care hospitals operating in Maryland do not provide pediatric services. As of July 1, 2001, there were 480 licensed pediatric beds in Maryland. The statewide occupancy for pediatric services, based on licensed beds, averaged 39.5 percent in calendar year 2000. There have been impressive declines in the utilization of hospital pediatric services over the past two decades. Between 1980 and 2000, the annual number of pediatric discharges from Maryland hospitals fell by 51 percent—from 46,685 to 22,948 (Refer to Table 1). Over this same time period, the average daily pediatric census declined by 65 percent—from 549 to 192 patients (Refer to Figure 1). These significant changes in pediatric utilization of acute care hospitals have occurred due to advances in medical technology as well as changes in physician practice patterns. Moreover, these dramatic declines in hospital utilization have occurred despite moderate growth in the population under 15 years of age. As a consequence, only four of the 33 Maryland hospitals with pediatric units had an average daily census of 10 or more patients in calendar year 2000. Eighteen of the 33 hospitals had an average daily census of 2 or fewer patients in 2000 (Refer to Table 2). This data suggests that there were many days when hospital pediatric units had no patients.

In support of deregulating pediatric services from CON review, commenters argued on the one hand that pediatric services are a basic service that each hospital should be able to provide without obtaining a CON; and, on the other hand, that pediatrics is highly specialized and increasingly concentrated in a small number of hospitals. It is also argued that because other more sophisticated services, such as neurosurgery, do not require CON review that it is inappropriate to regulate pediatric services. Staff does not believe that the fact that neurosurgery and other types of medical and surgical care are not now regulated at all supports deregulating pediatric services. It may, in fact, be more appropriate to study to need to regulate neurosurgery and other sophisticated services. Staff does not agree that HB 994 demonstrates that the General Assembly is not concerned with the development of small pediatric services. The optimal size of pediatric units was not considered in HB 994. Given utilization trends for pediatric services, it is clear that not all hospitals should provide inpatient pediatric services. Staff believes that the potential disadvantages of deregulating pediatric services from CON review outweigh the advantages.

Table 1
Trends in Pediatric Hospital Beds and Utilization: Maryland 1980-2000

Year	Number of Acute Care Hospitals	Licensed Pediatric Beds	Total Population 0-14 Years	Pediatric Discharges	Pediatric Patient Days	Average Length of Stay	Average Daily Census	Discharges Per 1,000 Population	Patient Days Per 1,000 Population
1980	53	882	921,768	46,685	201,093	4.31	549	50.65	218.16
1981	53	882	917,892	42,840	183,510	4.28	503	46.67	199.93
1982	54	922	913,824	42,794	174,602	4.08	478	46.83	191.07
1983	54	997	913,198	43,636	170,535	3.91	467	47.78	186.74
1984	54	1,005	915,999	40,722	153,538	3.77	420	44.46	167.62
1985	54	1,005	918,602	37,285	133,607	3.58	366	40.59	145.45
1986	53	819	924,692	35,738	134,406	3.76	368	38.65	145.35
1987	53	797	938,138	34,320	130,925	3.81	359	36.58	139.56
1988	53	766	959,080	33,500	123,883	3.70	338	34.93	129.17
1989	52	765	977,751	35,059	130,277	3.72	357	35.86	133.24
1990	52	777	990,001	34,671	125,011	3.61	342	35.02	126.27
1991	53	774	1,008,795	32,663	117,189	3.59	321	32.38	116.17
1992	51	715	1,027,589	30,661	109,419	3.57	299	29.84	106.48
1993	52	723	1,046,382	29,349	101,698	3.47	279	28.05	97.19
1994	51	745	1,065,176	28,257	95,112	3.37	261	26.53	89.29
1995	50	732	1,083,970	28,448	91,643	3.22	251	26.24	84.54
1996	50	708	1,088,089	26,117	83,712	3.21	229	24.00	76.93
1997	50	708	1,092,208	26,268	80,640	3.07	221	24.05	73.83
1998	50	696	1,096,328	22,909	71,267	3.11	195	20.90	65.01
1999	50	698	1,100,447	25,407	76,109	3.00	209	23.09	69.16
2000	47	485	1,104,566	22,948	70,150	3.06	192	20.78	63.51

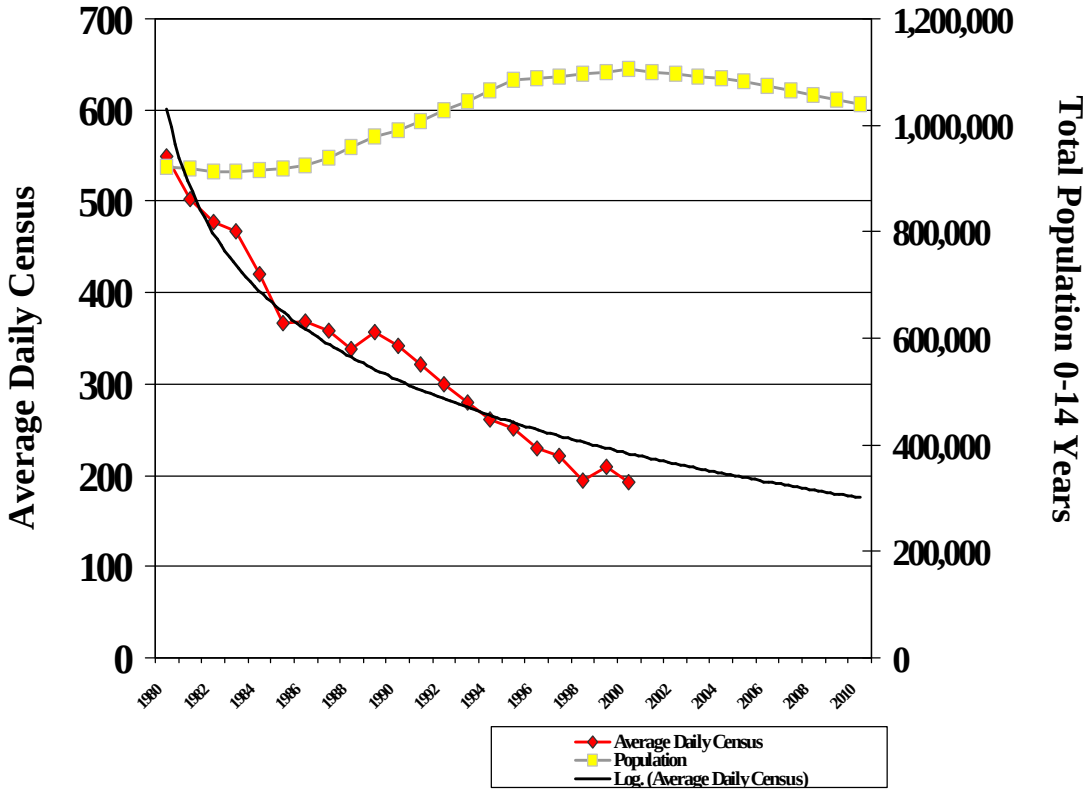
Source: Maryland Health Care Commission (Data reported on hospital utilization is from the Hospital Discharge Abstract Data Base for calendar years 1980-2000; population data reported is based on data from the Maryland Department of Planning, Population Estimates and Projections, Revised February 2000; and data on licensed acute care is from MHCC inventory files.)

Table 2
Hospital Pediatric Service Average Daily Census: Maryland, 2000

Hospital	Pediatric Discharges	Pediatric Patient Days	Average Daily Census
JOHNS HOPKINS HOSPITAL	5,125	25,885	71
U OF MD HOSPITAL	1,893	9,378	26
SINAI HOSPITAL	1,392	3,816	10
SHADY GROVE HOSPITAL	1,384	3,620	10
HOLY CROSS HOSPITAL	1,130	2,261	6
ANNE ARUNDEL MED. CTR.	1,002	1,968	5
ST. AGNES HEALTHCARE	770	1,749	5
WASHINGTON CTY. HOSPITAL	653	1,569	4
PENINSULA REGIONAL MED CTR	597	1,368	4
FRANKLIN SQUARE HOSPITAL	776	1,333	4
HARBOR HOSPITAL CENTER	558	1,235	3
PRINCE GEORGE'S HOSP. CTR.	442	1,135	3
MEMORIAL OF CUMBERLAND HOSP.	528	1,047	3
MEM. HOSP. AT EASTON	520	1,035	3
HOWARD CTY. GENERAL HOSPITAL	523	975	3
SAINT JOSEPH HOSPITAL	339	911	2
JOHNS HOPKINS BAYVIEW MED. CTR	257	877	2
FREDERICK MEMORIAL HOSPITAL	415	850	2
UNION MEMORIAL HOSPITAL	403	822	2
GREATER BALTIMORE MED. CTR.	424	813	2
CARROLL CTY. GENERAL HOSPITAL	374	808	2
MERCY MEDICAL CENTER	318	737	2
NORTH ARUNDEL HOSPITAL	305	628	2
CIVISTA MEDICAL CENTER	302	613	2
SOUTHERN MARYLAND HOSPITAL	302	602	2
UNION OF CECIL HOSPITAL	293	575	2
ST. MARY'S HOSPITAL	279	455	1
KENT & QUEEN ANNE'S HOSPITAL	160	383	1
CALVERT MEMORIAL HOSPITAL	169	289	1
GARRETT CTY. MEM. HOSPITAL	125	246	1
SUBURBAN HOSPITAL	147	226	1
UPPER CHESAPEAKE MED. CTR.	122	215	1
MONTGOMERY GENERAL HOSPITAL	44	70	0

Source: Maryland Health Care Commission (Data reported on hospital utilization is from the Hospital Discharge Abstract Data Base for calendar year 2000. Pediatric patients refer to patients 0-14 years of age not classified in the obstetric or psychiatric services.)

Figure 1
Pediatric Average Daily Census and Population Growth in the 0-14 Year Age Group: Maryland, 1980-2000 and 2010



Source: Maryland Health Care Commission, Hospital Discharge Abstract Data Base, Calendar Years 1980-2000; and, Maryland Office of Planning, Population Estimates and Forecasts, Updated February 2000.

III. Staff Recommendations

Analysis of the public comments received on the options identified in the working paper suggest strong support for maintaining existing Certificate of Need regulation for medical-surgical and pediatric services offered by acute care hospitals.

1. The Commission should continue its regulatory oversight of acute inpatient medical-surgical and pediatric services through the Certificate of Need program.
2. The Commission should recommend to the General Assembly that the current capital expenditure threshold in statute of $1,250,000 be increased to $2,500,000 for acute care hospitals.